James E. Cecchi Lindsey H. Taylor Donald A. Ecklund Kevin Cooper CARELLA, BYRNE, CECCHI, OLSTEIN, BRODY & AGNELLO, P.C. 5 Becker Farm Road Roseland, NJ 07068 (973) 994-1700

Steve W. Berman Hannah W. Brennan Mark T. Vazquez HAGENS BERMAN SOBOL SHAPIRO LLP 1301 2nd Ave., Suite 2000 Seattle, WA 98101 (206) 623-7292

Attorneys for Plaintiffs

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UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE INSULIN PRICING LITIGATION

Civil Action No. 2:17-cv-00699 (BRM)(ESK)

PLAINTIFFS' OPPOSITION TO DEFENDANTS' MOTION TO EXCLUDE THE TESTIMONY OF PROFESSOR MEREDITH ROSENTHAL

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I. INTRODUCTION

Dr. Meredith Rosenthal—one of the nation's leading healthcare economists—prepared an expert report that the plaintiffs submitted in support of class certification. In that report, Dr. Rosenthal defines the class period for each product, provides aggregate damages calculations for each defendant, and explains how she will identify class members and measure their overpayments.

To define the class period, Dr. Rosenthal employs a common form of regression analysis—the structural break (or "trend break") test. Taught to virtually all statistics and economics students, the analysis serves narrow ends: to define with scientific precision *when* some trend over time changed in a significant way. Because trends exist in every discipline, the test has appeared in literature spanning the entirety of the natural and social sciences. And because the test focuses on establishing *when* something changed, courts have held it to be a "widely used and reliable methodology" to determine the class period by examining the effects of defendants' conduct (prices, output, etc.) over time.

The defendants dance around this reality, exposing the frailties of their attacks with how much they *don't* say. They offer not one case analogy, relying on generic *Daubert* principles and out-of-context quotes from inapposite authority. The

¹ In re Broiler Chicken Antitrust Litig., 2022 WL 1720468, at *8 (N.D. Ill. May 27, 2022).

defendants do not address any court decision specifically dealing with or admitting structural break analyses. Their brief even avoids acknowledging the existence of the test, despite their own expert's familiarity with it.

Incredulously, the defendants accuse Dr. Rosenthal of "inventing" the methodology for this litigation. Putting aside that their own experts contradict this claim, one need only spend a few minutes searching online to discover articles, class materials, presentations, videos, and webpages that prove the absurdity of the charge. Spend a few minutes more on legal research, and one can find similar cases where courts admit the test under *Daubert*. The defendants have no excuse for failing to address these facts and precedents in their opening brief. And they have no basis for declaring the structural break methodology unreliable.

The defendants fare no better attacking Dr. Rosenthal's damages model. The defendants may quibble with Dr. Rosenthal's results or exemplar calculations, but case law makes clear that these do not provide a legal basis for the remedy they seek. To exclude testimony, the defendants must show the method—that is, how Dr. Rosenthal reached those results—is unreliable. Defendants don't attempt this, dooming their motion.

What's more, the defendants never provide a legal basis for the proposition that Dr. Rosenthal's damages model must account for their theory of "alternative" causes." That's because, by "alternative causes," defendants mean causes of other

injuries that are not the subject of the lawsuit, such as an insurer's decision not to pass through rebates to members. Defendants admit they have sole control over the list prices of the relevant analog insulins, which confirms that only they could cause the injuries relevant here.

In short, Dr. Rosenthal defines the class period using a common econometrics test that has been used in similar cases for the same purpose. Her damages model can accurately identify injured class members who paid based on the defendants' inflated list prices. And she can determine the amount those class members would have paid in the but-for world. If the defendants wish to cross-examine Dr. Rosenthal about some of her conclusions, they may do so at trial. The present motion, however, fails to successfully challenge *how* she reaches those conclusions, which it must. It should therefore be denied.

II. BACKGROUND

Dr. Meredith Rosenthal is the C. Boyden Gray Professor of Health Economics and Policy at the Harvard T.H. Chan School of Public Health.² In her role at Harvard, she teaches health economics and policy courses to undergraduate, Masters, and Ph.D. students.³ She has done extensive research focusing primarily on

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² Declaration of Meredith Rosenthal, Ph.D. in Support of Class Certification ("Rosenthal Report"), ¶ 3 (Dkt. No. 525-1, Exhibit 1).

³ Rosenthal Report, ¶ 4.

the economics of the health care and pharmaceutical industries, and has published hundreds of peer-reviewed journal articles, essays, and book chapters on this subject.⁴

Plaintiffs have asked Dr. Rosenthal to "(1) describe in economic terms the list-price increase scheme orchestrated by the defendants, (2) assess how this scheme benefited the defendants and other major actors in the pharmaceutical supply chain while imposing costs on consumers, (3) evaluate the economic impact of this scheme on class members, (4) apply statistical methods to determine the date or dates when the injury to class members began, and (5) calculate damages."⁵

To accomplish number four, Dr. Rosenthal uses a structural break test. This test is a "cornerstone of quantitative analysis," with its own chapter in the definitive econometrics handbook.⁶ The structural break test aims to "identify[] statistically significant trend breaks." In other words, the test examines a trend over time, and then determines if and when that trend changed in a significant way. To this end,

⁴ Rosenthal Report, ¶¶ 3-4.

⁵ Rosenthal Report, ¶ 1.

⁶ Expert Rebuttal Report of Meredith Rosenthal, Ph.D. In Support of Class Certification ("Rosenthal Rebuttal"), ¶ 108 n.203 (Attached as Exhibit 1 to the Declaration of Steve W. Berman In Support of Plaintiffs' Opposition To Defendants' Motion To Exclude The Testimony of Professor Meredith Rosenthal ("Berman Decl.")).

⁷ *Id.* ¶ 107.

the test is "a standard, professionally accepted statistical method" commonly employed "in a wide variety of settings."

In the context of this litigation, the plaintiffs allege, the evidence shows, and the defendants admit that around 2014, the drug manufacturers began raising list prices considerably so they could offer larger rebates to PBMs to get on exclusive formularies, widening the list-to-net price spread for each analog insulin product. So to determine when that spread changed significantly with statistical rigor, Dr. Rosenthal first examines the trend over time between each product's list price and average net price, determining a ratio. 10 Then, she tests the "hypothesis that there is no trend break in [that ratio] in a given quarter" using a statistical method known as the Wald Test. 11 The Wald Test yields several dates that reject this null hypothesis that is, several dates that demonstrate a significant break from the trend in the ratio between list and net prices. Of these, Dr. Rosenthal's method chooses the trend break for which the evidence rejecting the null hypothesis is strongest—a conservative measure, as merely selecting the earliest date would lead to increased damages. 12 Having selected a trend break date for each product, Dr. Rosenthal labels the time

⁸ *Id.* ¶¶ 108-09.

⁹ See Pls.' Motion for Class Certification at 13-18.

¹⁰ Rosenthal Report, ¶ 114.

¹¹ *Id.*

¹² *Id*.

before the trend break as the pre-period, and the time after the trend break as the post-period.¹³

Dr. Rosenthal creates a but-for world without the alleged conduct to determine damages. She does this by effectively extending the ratio between the list and net price in the pre-period into the post-period, as if the trend break never occurred. Specifically, she "tak[es] the average ratio of the AWP to the net price in the four quarters prior to the post-period," and then applies this ratio "to the net price in the post-period." Dr. Rosenthal can then substitute this but-for-AWP for the actual-AWP as the basis for the transactions of injured class members. ¹⁵

III. LEGAL STANDARD

The admissibility of expert testimony rests on three inquiries: (1) the qualifications of the expert, (2) the reliability of the methodology that the expert applied, and (3) the capacity of the proffered testimony to assist the trier of fact on an issue.¹⁶ Defendants do not challenge Dr. Rosenthal's qualifications, nor whether her testimony will assist the trier of fact; they focus solely on the second inquiry.¹⁷

¹³ Id.

¹⁴ Id. ¶ 118.

¹⁵ *Id.* ¶¶ 118-19.

¹⁶ Pineda v. Ford Motor Co., 520 F.3d 237, 244 (3d Cir. 2008).

¹⁷ See Defs.' Br. at 12-13.

The Third Circuit emphasizes "that 'the standard for determining reliability is not that high," and cautions the district court to "demonstrate the appropriate level of flexibility required by Rule 702."18 Relevant factors to the analysis include: "(1) whether a method consists of a testable hypothesis; (2) whether the method has been subject to peer review; (3) the known or potential rate of error; (4) the existence and maintenance of standards controlling the technique's operation; (5) whether the method is generally accepted; (6) the relationship of the technique to methods which have been established to be reliable; (7) the qualifications of the expert witness testifying based on the methodology; and (8) the non-judicial uses to which the method has been put."19 That said, these considerations "are neither exhaustive nor applicable in every case." ²⁰ In applying these factors, the court focuses "on the expert's methods and reasoning," not on the expert's credibility, 21 or "whether a particular scientific opinion has the best foundation or whether it is demonstrably

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¹⁸ Pineda, 520 F.3d at 247-248 (quoting In re TMI Litig., 193 F.3d 613, 665 (3d Cir. 1999)).

¹⁹ *Id.* at 247-48.

²⁰ Id. at 248 (quoting Kannankeril v. Terminix Int'l, Inc., 128 F.3d 802, 806 (3d Cir. 1997), as amended (Dec. 12, 1997)).

²¹ *Id.* at 247.

correct."²² Instead, "[t]he analysis of the conclusions themselves is for the trier of fact when the expert is subjected to cross-examination."²³

Deference to expertise is particularly appropriate for "soft sciences like economics" and statistics because they often involve "matters in which reasonable experts may differ." Even if the data relied on by the expert is imperfect, and more (or different) data might have resulted in a 'better' or more 'accurate' estimate in the absolute sense, it is not the district court's role under *Daubert* to evaluate the correctness of facts underlying an expert's testimony." Finally, at class certification, the test is relaxed because "[t]he main purpose of *Daubert* exclusion is to protect juries from being swayed by dubious scientific testimony" and "[t]hat interest is not implicated at the class certification stage where the judge is the decision maker."

²² Oddi v. Ford Motor Co., 234 F.3d 136, 145-46 (3d Cir. 2000).

²³ Id. (quoting Kannankeril, 128 F.3d at 806).

²⁴ Hughes v. The Ester C Co., 317 F.R.D. 333, 341 (E.D.N.Y. 2016); see also In re Air Cargo Shipping Servs. Antitrust Litig., 2014 WL 7882100, at *8 (E.D.N.Y. Oct. 15, 2014) (certain fields "require the use of professional judgment," and "is less likely to be excluded"), rept. and recomm. adopted, 2015 WL 5093503 (E.D.N.Y. July 10, 2015).

²⁵ In re Mushroom Direct Purchaser Antitrust Litig., 2015 WL 5767415, at *12 (E.D. Pa. July 29, 2015) (quotation omitted).

²⁶ In re Zurn Pex Plumbing Prods. Liab. Litig., 644 F.3d 604, 613 (8th Cir. 2011); see also SE Prop. Holdings, LLC v. Ctr., 2017 WL 242610, at *3 (S.D. Ala. Jan. 19, 2017) ("[T]here is less need for the gatekeeper to keep the gate when the gatekeeper is keeping the gate only for himself."); see also Universe Antiques, Inc. v. Vareika, 2011 WL 5117057, at *6 (S.D.N.Y. Oct. 21, 2011) (same).

IV. ARGUMENT

- A. The structural break test is a widely accepted method to detect the point at which some trend over time changes in a significant way.
 - 1. Courts often permit experts in class actions to rely on structural break analyses to define the period in which the allegedly unlawful conduct occurred—the same purpose offered by Dr. Rosenthal.

In her expert report, Dr. Rosenthal employs a standard statistical regression analysis: a structural break (or "trend break") test. While the defendants accuse Dr. Rosenthal of "inventing" this test for this litigation, in truth, she uses a method so common it has its own chapter in the definitive econometrics handbook.²⁷ One website offers thousands of academic articles either on the subject, employing the methodology, or discussing it.²⁸ Ironically, even defendants' expert is familiar with structural break tests.²⁹

Naturally, then, the structural break test meets all the criteria for reliability under *Daubert*: (1) it can be tested; (2) has been subjected to peer review and publication; (3) has a known rate of error and standards controlling its operation; and (4) has acceptance within the relevant scientific community.³⁰

²⁷ Rosenthal Rebuttal ¶ 108 n.203.

²⁸ See

https://www.jstor.org/action/doBasicSearch?Query=%22structural+break%22&so=rel.

²⁹ See Expert Report of M. Laurentius Maria, Ph.D. ("Marais Report") \P 12 (describing the Supremum Wald Test).

³⁰ Rosenthal Rebuttal ¶¶ 107-120.

As the name suggests, the test detects a structural break—a point at which a variable increases or decreases at a rate significantly different than it had in the past.³¹ Specifically, the analysis determines a trend in a time series, and then applies statistical methods to confirm whether that trend diverges.³² In short, a structural break test establishes, with a reasonable degree of scientific precision, *if and when* some trend changed in a significant way, a result that proves useful in a variety of real-world applications, including economics, finance, investing, lawmaking, public health, epidemiology, sales, and marketing.

For instance, public health experts can look at the trend in auto fatalities over many years to see if a sudden drop in deaths means seatbelt legislation had a positive effect.³³ Criminology experts can use trend break analyses to determine if and when the rate of youth homicides dropped in Boston and compare that to the timing of targeted initiatives to curb the problem.³⁴ And in monetary policy, the existence and

³¹ Rosenthal Rebuttal ¶¶ 107-08.

³² Id.

³³ Richard A. Davis, Thomas Lee, Gabriel Rodriguez-Yam, Structural Break Detection in Time Series Structural Break Detection in Time Series, at 31, available at http://www.stat.columbia.edu/~rdavis/lectures/Cyprus2_04.pdf.

³⁴ See Piehl, Anne Morrison, Suzanne J. Cooper, Anthony A. Braga, and David M. Kennedy. "Testing for Structural Breaks in the Evaluation of Programs." The Review of Economics and Statistics 85, no. 3 (2003): 550–58.

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timing of structural breaks in inflation can indicate whether certain policies have the desired effect.³⁵

Given its utility in showing when some change in a trend occurred with scientific precision, federal courts have widely admitted structural break analyses by experts as evidence of the class period, damages, or causation. ³⁶ The district court in In re Broiler Chicken Antitrust Litigation recently admitted structural break evidence to determine the class period over many of the same objections offered by defendants here. In Broiler Chicken Antitrust, the consumer plaintiffs alleged that various consumer chicken meat producers conspired to raise the prices of their products by, among other things, coordinating to reduce the supply of Broiler chickens.³⁷ To identify the class period and support their theory of causation, the consumer plaintiffs' expert used a structural break test to pinpoint when the "historic decrease

³⁵ See Genc, Ismail H., and Mehmet Balcilar. "Effectiveness of Inflation Targeting in Turkey." Emerging Markets Finance & Trade, vol. 48, 2012, pp. 35-47.

³⁶ E.g., In re Namenda Direct Purchaser Antitrust Litig., 331 F. Supp. 3d 152, 178 (S.D.N.Y. 2018) (holding structural break test could reliably show "evidence of causation in support of Plaintiffs' theory"); In re Rail Freight Fuel Surcharge Antitrust Litig., 292 F. Supp. 3d 14, 57 (D.D.C. 2017), aff'd, 934 F.3d 619 (D.C. Cir. 2019) (admitting expert testimony to "show the existence of a statistically significant structural break in [the relationship between freight rates and fuel prices]" as means of proving damages and class period); In re Syngenta AG MIR 162 Corn Litig., 2016 WL 5371856, at *10 (D. Kan. Sept. 26, 2016) (admitting structural break analysis that looked at "historic break" between corn prices and milo prices).

³⁷ In re Broiler Chicken Antitrust Litig., 2022 WL 1720468, at *1.

in Broiler production" occurred in the market relative to trends from 2000 to 2020.³⁸ The district court denied the defendants' motion to exclude this testimony.³⁹

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As the court noted, the chicken producers couldn't attack the reliability structural break methodology itself, as there's "[no] dispute that structural break analysis is a widely used and reliable methodology."⁴⁰ Instead, the chicken producers could only argue that the method did not prove collusion caused the trend break where, according to the defendants, any number of lawful events could also explain the drop in production. ⁴¹ But as the court explained, the structural break analysis does not attempt to prove collusion *per se*, but answers two questions: (1) whether there was a statistically significant change in production and, (2) "if so, when was the most likely date on which this change occurred."⁴² From there, the trier of fact may "investigate the cause" and decide the lawfulness of the conduct.⁴³

³⁸ *Id.*, at *8.

³⁹ *Id.*, at *21.

⁴⁰ *Id.*, at *8; see also In re Rail Freight Fuel Surcharge Antitrust Litig., 292 F. Supp. 3d at 58 (in admitting expert testimony of a structural break, explaining that such "analysis is generally a reliable method for determining damages in antitrust cases and is a mainstream tool in economic study") (internal citations and quotations omitted) (emphasis added).

⁴¹ In re Broiler Chicken Antitrust Litig., 2022 WL 1720468, at *9.

⁴² *Id.*, at *8.

⁴³ *Id.*, at *10.

Ample authority supports the result in *Broiler Chicken Antitrust*. The *In re*Syngenta court held that structural break analysis provides a scientific basis for an expert's choice of a class period, thus satisfying the *Daubert* standard. Likewise, the *In re Namenda* court held that the structural break test could reliably show "evidence of causation in support of Plaintiffs' theory" by determining when a sudden change in prescription drug sales occurred and comparing that to evidence demonstrating the timing and intent of the alleged conduct. 45

The defendants avoid addressing Broiler Chicken Antitrust, In re Namenda, In re Syngenta, or In re Rail Freight Fuel Surcharge Antitrust. One need not be clairvoyant to understand why. These cases belie defendants' claim that the methodology lacks "general acceptance." They confirm the test's reliability, both in the general sense and for the purpose offered in this case. And they defeat defendants' motion.

2. Dr. Rosenthal doesn't opine on the legal question of whether defendants' conduct wasn't fair; she determines when the effects of the alleged conduct occurred using an established scientific method.

Through several passages of slippery phrasing, defendants *appear* to challenge Dr. Rosenthal's methodology as applied in this specific case under unfair practices

⁴⁴ In re Syngenta AG MIR 162 Corn Litig., 2017 WL 1738014, at *19 (D. Kan. May 4, 2017).

⁴⁵ In re Namenda Direct Purchaser Antitrust Litig., 331 F. Supp. 3d at 178.

laws (as compared to other cases under the Sherman Act). 46 Yet, to the extent defendants only vaguely suggest that the reliability of a structural break analysis hinges on the cause of action, they fail to explain why the legal theory so matters. Conceivably, defendants calculated that by not distinguishing this case from others they would not have to concede that courts have found the methodology reliable. But, by taking that route, defendants waive the argument altogether. 47

Still, the distinction is one without a difference. The structural break test has nearly limitless applications in fields as varied as sports, politics, and epidemiology, blunting the suggestion that a subtle change in legal theory somehow renders the methodology unreliable. More to the point, structural break tests determine the start of the class period in antitrust cases by evaluating when some significant change in

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⁴⁶ See Defs.' Br. at 2 ("Prof. Rosenthal is not using any recognized economic approach to detecting supposedly 'unfair' or 'unconscionable' pricing") (emphasis added); id. at 10 ("Her report does not identify anyone who has ever used this approach to measure purported 'unconscionable or unfair' conduct.") (emphasis added); id. ("Nor did she 'rely on any publications' or 'learned treatise' that endorse 'trend breaks' as a recognized methodology to identify 'unfair or unconscionable' pricing behavior or assess damages for such a claim in a lawsuit.").

⁴⁷ "It is hornbook law that arguments raised for the first time in a reply brief are waived[.]" Aiellos v. Zisa, 2009 WL 3486301, at *1 (D.N.J. Oct. 20, 2009); see also Valerino v. Hoover, 643 F. App'x 139, 142 (3d Cir. 2016) ("[The plaintiff] never requested that the matter be sent to arbitration, and, in any case, she waived this argument by failing to raise it [in the district court] until a reply brief on a Rule 60(b) motion.").

pricing or production occurs⁴⁸—precisely how Dr. Rosenthal uses it here in an unfair conduct case. Defendants never explain why the break test can accurately identify a marked change in pricing in an antitrust case but not in an unfair conduct case.

Put another way, the methodology analyzes *the effects of conduct*, not the conduct itself. ⁴⁹ One can conclude from a break test that "*something* happened" and investigate the reason for the change. But the test does not, by itself, "identify causes, collusive or otherwise." ⁵⁰ So even if the underlying legal theory were to shift from unfair pricing to price fixing, Dr. Rosenthal's methodology would not differ. Defendants' argument—or, more accurately, their *implied* argument—amounts to at most meaningless insinuation.

What's more, defendants have undercut their own attacks on the reliability of the methodology by going to "great lengths to identify a cause" for the very trend

⁴⁸ See, e.g., In re Rail Freight Fuel Surcharge Antitrust Litig., 292 F. Supp. 3d at 58 (finding expert's examination of the break in the relationship between freight rates and fuel prices to determine start of the conspiracy a "generally reliable" and "widely accepted method" to determine damages in an antitrust case).

⁴⁹ In re Namenda Direct Purchaser Antitrust Litig., 331 F. Supp. 3d at 178 ("Defendants complain that Dr. Lamb's structural break test fails because it does not isolate the cause of the February 2014 break. However, Dr. Lamb testified that the test was not designed to do so. He testified that '[the test] is not able to tease out where the source of the structural break comes from by itself. One has to implement it because one believes that there is some event which leads to a structural break."").

⁵⁰ In re Broiler Chicken Antitrust Litig., 2022 WL 1720468, at *9.

breaks that Dr. Rosenthal identifies.⁵¹ In response to the recent public outcry about their conduct, defendants have repeatedly explained that they kept analog insulin net prices flat while "aggressively" (in their words⁵²) raising list prices.⁵³ They blame others—namely, PBMs and insurers—for exacerbating this trend.⁵⁴ By doing so, they acknowledge that a trend break happened.

Not that the widening of the spread between list and net prices was any mystery in the first place. Visual representations of historical list-to-net price ratios make clear that at some point net prices (the red line) diverged significantly from list prices (the blue line).⁵⁵

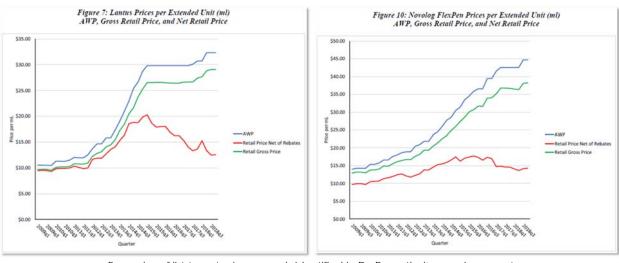
⁵¹ *Id.*, at *9.

⁵² See, e.g., Pls.' Motion for Class Certification at n.108, 117, 118, 124.

⁵³ E.g., Sanofi Prescription Medicine Pricing Principles, *available at* https://www.sanofi.com/dam/jcr:d41dfad7-a0a3-441d-98f3-c04c96192af2/Prescription-Medicine-Pricing-Principles.pdf (last visited Jul. 14, 2022); Bill Alpert, FTC Sets Its Sights on Prescription Drug Middlemen and the High Cost of Insulin, BARRONS.COM (June 21, 2022), https://www.barrons.com/articles/ftc-high-cost-of-insulin-51655832290.

⁵⁴ Pls.' Motion for Class Certification at 15-16.

⁵⁵ Rosenthal Report at 28, 31.



Examples of list-to-net price spreads identified in Dr. Rosenthal's opening report

Dr. Rosenthal's method simply helps identify when that break occurred with a reasonable degree of scientific precision. And if a "structural break test confirms the simple reality that is apparent to the naked eye," that "is a reason to find [the] analysis credible and persuasive, not to reject it." Defendants' motion to exclude the testimony of Dr. Rosenthal thus fails.

3. Defendants misrepresent the results of Dr. Rosenthal's trend break analysis, which nonetheless goes to the weight of the testimony, not its admissibility.

Defendants attempt to further discredit Dr. Rosenthal's structural break analysis by pointing to what they see as inconsistent or arbitrary results. But even if such attacks on the results of Dr. Rosenthal's methodology had merit—and they don't—that wouldn't support the relief defendants seek; "[t]he question of whether a study's results were properly calculated or interpreted ordinarily goes to the weight of

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⁵⁶ In re Broiler Chicken Antitrust Litig., 2022 WL 1720468, at *9.

the evidence, not to its admissibility."⁵⁷ Even "careless mistakes," "errors," "shoddy record keeping," "miscalculations," and "inaccuracies" do not suffice to render expert testimony unreliable because "they do not fundamentally undermine the methodologies."⁵⁸ Defendants can criticize Dr. Rosenthal's choices, conclusions, and results all they want. But these amount to "substantive disagreements," which defendants can "test[] on cross examination" at trial.⁵⁹ To *exclude* the testimony now, defendants must prove the structural break test lacks reliability, which they fail to do.

A common tactic of *Daubert* movants, the drug manufacturers conflate their criticisms of the expert report with questions regarding the reliability of the expert's methodology. For instance, the *In re:* Syngenta defendants challenged the results of a structural break analysis to determine the class period, characterizing the dates as "improperly 'cherry-picked'" and lacking a sufficient basis.⁶⁰ But the court soundly rejected those challenges as going to the weight of the opinions; the expert's "choice of event date [did] have a scientific basis—[the] structural break analysis."⁶¹

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⁵⁷ Karlo v. Pittsburgh Glass Works, LLC, 849 F.3d 61, 83 (3d Cir. 2017).

⁵⁸ See In re Johnson & Johnson Talcum Powder Prod. Mktg., Sales Pracs. & Prod. Litig., 509 F. Supp. 3d 116, 146 (D.N.J. 2020) (collecting cases holding that attacks on errors and results go to the weight of the testimony, not the admissibility).

⁵⁹ In re Front Loading Washing Mach. Class Action Litig., 2013 WL 3466821, at *8 (D.N.J. July 10, 2013).

⁶⁰ In re Syngenta AG MIR 162 Corn Litig., 2017 WL 1738014, at *19.

⁶¹ *Id.*, at *19.

Nevertheless, even though the defendants' critiques bear no relevance to the relief they seek, the arguments fall flat under scrutiny.

First, the idea that Dr. Marais detects trend breaks in the pre-period does not mean that Dr. Rosenthal's method is "preordained" to find trend breaks wherever it looks. As noted above, Dr. Rosenthal's methodology yields several candidates for trend breaks, and "selects the date at which the evidence rejecting the null hypothesis of no break in the trend of the AWP to net price ratio is **strongest**." Because Dr. Rosenthal did not simply choose the earliest possible trend break, there will necessarily be trend breaks in the pre-period; these "are the earlier breaks that [Dr. Rosenthal] did not choose."

Second, when the defendants state that Dr. Marais' finds breaks in *the* but-for world, they mean Dr. Marais finds breaks in *his* but-for world. As explained in Dr. Rosenthal's rebuttal report, Dr. Marais uses an alternative method—a linear extrapolation of the AWP-to-net-retail-price ration—to construct his own but-for world. Dr. Marais's attempt to point to these "these 'but-for worlds' [that] are his

 $^{^{62}}$ Rosenthal Rebuttal ¶ 109 (emphasis in original).

⁶³ *Id.* ¶ 110.

⁶⁴ *Id.* ¶ 114.

own construction, using a flawed methodology" does not disprove the reliability of Dr. Rosenthal's model. 65

Third, when the defendants argue that one may find trend breaks when comparing AWP and gross price, or when comparing list prices and pharmacy retail prices, they fail to explain how applying this method to a completely different set of data says anything about the test's reliability here.⁶⁶

Fourth, the defendants claim that so-called "minor" changes to Dr. Rosenthal's method produces "dramatically different results." But this means nothing. Of course, when one alters the basic inputs of an analysis, the results of the test will change.⁶⁷

Fifth, defendants criticize Dr. Rosenthal's method for finding different start dates for similar products. But that result is expected when the ratio of AWP-to-net-price varies by product—that is, the specific list price increase and rebate terms will not be the same for each defendant and each product.⁶⁸

In sum, none of defendants' attacks on the results of Dr. Rosenthal's trend break analysis undermine the method's reliability. At best, the defendants can, at the

⁶⁵ Id.

 $^{^{66}}$ Id. ¶ 117.

⁶⁷ *Id.* ¶ 119.

⁶⁸ *Id.* ¶ 113.

appropriate time, present these arguments to the jury when it weighs the probative value of Dr. Rosenthal's testimony. But that time is not now. The motion to exclude should thus be denied.

B. Defendants cannot meet their burden on a motion to exclude by mislabeling damages calculations as "mistakes" or "arbitrary."

Defendants do not challenge *the methods* employed by Dr. Rosenthal in her damages model. Rather, they claim they can prove her model unreliable by questioning results as "arbitrary," or pointing out "flaws" and "mistakes" for a single plaintiff. But even were one to accept defendants' labels, they carry no *legal* significance to the motion at hand; "contentions that the assumptions are unfounded go to the weight, not the admissibility, of the testimony." Defendants' entire challenge to Dr. Rosenthal's damages model falls under the category of

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⁶⁹ In re: Gen. Motors LLC Ignition Switch Litig., 2015 WL 9480448, at *1 (S.D.N.Y. Dec. 29, 2015); see also Washington v. Kellwood Co., 105 F. Supp. 3d 293, 306 (S.D.N.Y. 2015) ("Unless the information or assumptions that plaintiff's expert [] relied on were 'so unrealistic and contradictory as to suggest bad faith,' inaccuracies in the underlying assumptions or facts do not generally render an expert's testimony inadmissible.") (quoting R.F.M.A.S., Inc. v. So, 748 F. Supp. 2d 244, 269 (S.D.N.Y. 2010)).

"things they can explore on cross-examination at trial." They are not the proper subject of a *Daubert* motion. Nor do they stand on their merits.

4. Dr. Rosenthal's results are consistent with the notion that it's the unlawfulness of the underlying conduct that determines whether a class member may recover on a transaction.

Defendants have it backward. According to defendants, Dr. Rosenthal's damages model yields "nonsensical," "inconsistent," or "arbitrary" results because it may, in some instances, treat "essentially identical prices for the same products as both fair and legal at one point in time and yet 'unfair and unconscionable' at another." Yet, in an attempt to appeal to the Court's sensibilities, defendants overlook the obvious: plaintiffs allege unfair *practices*, not unfair prices.

In other words, class membership does not depend on the patient having paid some threshold *amount*; it depends on whether the patient paid *a price inflated by defendants' conduct*. So it may be that two people paid nearly identical sums for the same insulin, but one person falls in the class and the other doesn't. That's because

⁷⁰ Southwire Co. v. J.P. Morgan Chase & Co., 528 F. Supp. 2d 908, 935 (W.D. Wis. 2007) (rejecting the claim that double-counting, errors, or inconsistencies in the damages calculations provided "grounds for excluding evidence").

⁷¹ Daubert v. Merrel Dow Pharms., Inc., 509 U.S. 579, 596 (1993) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

⁷² Defs.' Br. at 21-24.

in the former instance the individual paid for insulin based on an inflated list price, and in the latter example, the person did not. The fact that the totals nearly match is coincidental. It could be because one person paid a copay and the other coinsurance, or because one bought just before the class period and the other just after. Either way, the results don't conflict. Such quirks are an expected consequence where injury flows from the unlawful conduct, and not the other way around.

The irony is that had Dr. Rosenthal done as defendants suggest and drawn a line demarcating fair and unfair prices without considering how those prices relate to the allegations, *that* would have been arbitrary. But as she's developed a method to successfully link overpayments of class members to the misconduct—a method defendants don't bother to challenge—defendants can merely nitpick with the results.

5. Defendants' characterizations of the Bozzell example do not undermine the reliability of Dr. Rosenthal's damages model.

Defendants further attempt to undermine Dr. Rosenthal's damages model by pointing to perceived mistakes in her damages calculations for one named plaintiff, Carole Andrew Bozzell, who appears on behalf of her minor son. But the so-called "mistake" occurs *not* in Dr. Rosenthal's method, but in that particular plaintiff's online records.

Dr. Rosenthal sought to show how she would calculate damages for absent class members using named plaintiffs as examples. Because the nonparties who

produced the transactional data deidentified them at this stage for privacy reasons, Dr. Rosenthal had to use the named plaintiffs' own collection of receipts or printouts as stand-ins. In the instance of Bozzell, certain records turned out to be inadequate substitutes for complete data.⁷³

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But crucially, Dr. Rosenthal's damages calculations will ultimately not rely on a given patient's mélange of online printouts.⁷⁴ Rather, Dr. Rosenthal will rely on detailed transactional data from: (1) the largest PBMs, representing over 90% of the insureds in the U.S.; (2) the major pharmacies, where the vast majority of analog insulin sales occurred; and (3) data from the third-parties hired by defendants to

See Rosenthal Rebuttal ¶¶ 143-44.

⁷³ The named plaintiffs' circumstances were unique. Having ordered insulin through the mail, the medication spoiled being left outside unrefrigerated. The plaintiff sought a replacement. However, the online printout of the transaction showed that the plaintiff paid the full amount for this replacement when, in fact, it was provided free of charge.

⁷⁴ While the plaintiffs' trial plan allows certain class members to come forward and present evidence of qualifying purchases, the overwhelming majority of these transactions will be locatable in the data, given that the major PBM data covers roughly 94% of insureds (see HIRC, Pharmacy Benefit Managers: Market Landscape and Strategic Imperatives (2022), available at https://www.hirc.com/system/files/public/MM_PBM%20Landscape_2022.pdf) and major retail pharmacy data accounts for more than 70% of pharmacy transactions (see Top U.S. pharmacies ranked by prescription drugs market share in 2021, STATISTA, https://www.statista.com/statistics/734171/pharmacies-ranked-by-rx-market-share-in-us/ (last visited Sept. 8, 2022)). For example, uninsured cash payers who purchased at small, local pharmacies can prove their purchases using detailed receipts and an affidavit.

track their affordability programs.⁷⁵ The transactional data in this area is rich with information, including columns that can, among other things, identify the purchaser, date, NDC, amount paid, or whether it was a copay, coinsurance, or Medicaid transaction. Once fully identified with patient information, the data can then be consolidated and cross-checked, allowing Dr. Rosenthal to eliminate duplicate transactions or transactions under defendants' affordability programs.⁷⁶ All told, the wealth of transactional data does not pose the problems that would occur if the class did, in fact, need to entirely rely on incomplete printouts.

So defendants' attacks on the Bozzell example say nothing about the reliability of the methodology. At best, defendants' contentions amount to a criticism of the quality of the data on which Dr. Rosenthal relied in that specific example, even though these are not the inputs Dr. Rosenthal eventually will use. Following certification, Dr. Rosenthal will have a full set of identified transactional data. But at this point, her opinions and methodology satisfy Rule 23.

⁷⁵ Rosenthal Rebuttal ¶ 6.

 $^{^{76}}$ See Supplemental Declaration of Mark D. Fischer of Rawlings Analytics, LLC $\P\P$ 4-10 (attached as Exhibit 2 to the Berman Decl.).

C. Defendants have sole control over the list prices of their drugs, revealing the proposition that the damages model should account for "alternative causes" to be dubious.

Defendants assert that Dr. Rosenthal failed to consider "alternative causes" of class members' overpayments in her damages model because she attributes the "entire injury" to defendants, rather than other potential actors in the supply chain. 77 This argument, however, miscomprehends plaintiffs' allegations, their injury, and the damages model itself.

Plaintiffs allege that defendants inflated the list price of their insulins on a captive market so they could pay kickbacks to middlemen and avoid competitive pressures, creating colossal spreads between the list and net prices of the drugs.

Defendants admit to this conduct and to the fact that they—and only they—control the list prices of their drugs. Plaintiffs define the class to solely include those who purchased defendants' analog insulins by paying the list price (or some percentage of the same). And, because defendants' list price has a direct, formulaic effect on prices at the pharmacy, Dr. Rosenthal's model can accurately measure the unlawful overpayment attributable to defendants' conduct in the price paid. In short, no

⁷⁷ Defs.' Br. at 26.

⁷⁸ Pls.' Motion for Class Certification at 15-16.

 $^{^{79}}$ See Rosenthal Report ¶ 123 ("[T]he but-for coinsurance is equal to the ratio of the but-for AWP divided by the actual AWP, multiplied by the actual coinsurance payment.").

"alternative causes" exist, as plaintiffs' injury derives from actions over which only defendants have control, and the damages model measures only that injury.

Defendants, it appears, believe Dr. Rosenthal's model must also account for PBMs and insurers not passing on the "benefits" of rebates to patients, for example, through lower premiums. ⁸⁰ But the PBMs and insurers aren't defendants in this case. And defendants offer nothing to support the claim that the supposed moral failings of the PBMs and insurers entitle them to some sort of legal offset.

Indeed, as a matter of law, defendants present no authority remotely on point, made evident by the fact that they lead with personal injury cases involving differential diagnoses—a test that by its very nature involves "considering *plausible* alternative causes" of a physical ailment and then eliminating them to settle on a single cause.⁸¹ Likewise, other cases that exclude expert testimony on such grounds

⁸⁰ Defendants can't make up their mind. In their *Daubert* brief, defendants argue the insurers' failure to pass on benefits amounts to an "alternative *cause*" of plaintiffs' injuries; in the class response brief, defendants speculate that rebates provide trickle-down benefits to members through insurers that *offset* plaintiffs' injuries.

⁸¹ Magistrini v. One Hour Martinizing Dry Cleaning, 180 F. Supp. 2d 584, 609 (D.N.J. 2002), aff'd, 68 F. App'x 356 (3d Cir. 2003) (emphasis added); see also Rimbert v. Eli Lilly & Co., 2009 WL 2208570, at *20 (D.N.M. July 21, 2009) (excluding expert for not adequately performing differential diagnosis); Salamone v. Wal-Mart Stores E., LP, 2011 WL 2787788, at *3 (E.D. Pa. July 15, 2011) (Medical expert "proceeded with no information concerning the plaintiff's medical history that pre-dates her alleged injury.").

do so for ignoring "obvious" sources of the same injury plaintiffs' allege.⁸² Those cases do not support defendants' proposition here: that an expert's damages model must account for how other actors may have harmed plaintiffs in a different way.

As a matter of logic, defendants' argument also collapses. First, insurers save by virtue of lower prices, not lower prices *because of rebates*. So, it does not follow that defendants' rebate scheme generated benefits that wouldn't also exist in the but-for world. Even so, the defendants lament a monster of their own making. They *created* this system with colossal list prices and secret rebates, throwing diabetics to the mercy of others to avoid overpaying for insulin. The defendants can't pass the buck to those third parties and evade legal responsibility where the expected consequences of their scheme came to fruition.

In truth, when defendants mention "alternative causes," they more accurately speak of blame apportionment. Yet, while defendants may very well believe the role of PBMs and insurers mitigates their own responsibility, they can play that argument for a jury. Nothing requires the plaintiffs to incorporate defendants' finger-pointing into their damages model now under the guise of "causation."

⁸² Discover Fin. Servs. v. Visa U.S.A., Inc., 582 F. Supp. 2d 501, 505 (S.D.N.Y. 2008) (emphasis added).

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V. CONCLUSION

The defendants seek the extreme relief of striking Dr. Rosenthal's entire report without even grappling with the methodologies she employs. They disregard the science supporting her method for determining the class period—a form of regression analysis—in a futile attempt to portray it as novel. And instead of challenging Dr. Rosenthal's damages methodology head on, the defendants do no more than mischaracterize the results with legally meaningless and conclusory labels. At best, the defendants have previewed for the Court how they would cross-examine Dr. Rosenthal. But they have not cast any doubt on the reliability of her methods. For these reasons, the Court should deny the defendants' motion to exclude.

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HAGENS BERMAN SOBOL SHAPIRO LLP

/s/ Steve W. Berman

Steve W. Berman

1301 2nd Avenue, Suite 2000

Seattle, WA 98101

Telephone: (206) 623-7292

Facsimile: (206) 623-0594

steve@hbsslaw.com

Thomas M. Sobol

Hannah W. Brennan

55 Cambridge Parkway, Suite 301

Cambridge, MA 02142

Telephone: (617) 482-3700

Facsimile: (617) 482-3003

tom@hbsslaw.com

hannahb@hbsslaw.com

Mark T. Vazquez

455 N. Cityfront Plaza Dr., Suite 2410

Chicago, IL 60611

Telephone: (708) 628-4962

Facsimile: (708) 628-4952

markv@hbsslaw.com

Respectfully submitted,

CARELLA, BYRNE, CECCHI,

Olstein, Brody & Agnello, P.C.

/s/ James E. Cecchi

James E. Cecchi

Lindsey H. Taylor

Donald A. Ecklund

5 Becker Farm Road

Roseland, NJ 07068

Telephone: (973) 994-1700

Facsimile: (973) 994-1744

jcecchi@carellabyrne.com

ltaylor@carellabyrne.com

decklund@carellabyrne.com

Attorneys for Plaintiffs and Interim Co-Lead Counsel for the Class -

CERTIFICATE OF SERVICE

I certify that on September 14, 2022, I caused this Opposition to

Defendants' Motion to Exclude the Testimony of Professor Meredith Rosenthal
to be served on ALL DEFENSE COUNSEL OF RECORD via email.

<u>/s/ Steve W. Berman</u> Steve W. Berman